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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-R-64, CMS-1957, and CMS-10169]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS) is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Indirect Medical Education (IME) and Supporting Regulations at 42 CFR 412.105; Direct Graduate Medical Education (GME) and Supporting Regulations at 412 CFR 413.75 through 83; Use: Section 1886(d)(5)(B) of the Social Security Act (the Act) requires additional payments to be made under the Medicare Prospective Payment System (PPS) for the indirect medical educational costs a hospital incurs in connection with interns and residents (IRs) in approved teaching programs. In addition, Title 42, Part 413,

sections 75 through 83 implement section 1886(d) of the Act by establishing the methodology for Medicare payment of the cost of direct graduate medical educational activities. These payments, which are adjustments (add-ons) to other payments made to a hospital under PPS, are largely determined by the number of full-time equivalent (FTE) IRs that work at a hospital during its cost reporting period. In Federal fiscal year (FY) 2011, the estimated Medicare program payments for indirect medical education (IME) costs amounted to \$6.59 billion. Medicare program payments for direct graduate medical education (GME) are also based upon the number of FTE-IRs that work at a hospital. In FY 2011, the estimated Medicare program payments for GME costs amounted to \$2.57 billion. Form Number: CMS-R-64 (OCN: 0938-0456); Frequency: Reporting – Annually; Affected Public: Private Sector – Business or other for-profits and Not-for-profit institutions; Number of Respondents: 1,075; Total Annual Responses: 1,075; Total Annual Hours: 2,150. (For policy questions regarding this collection contact Milton Jacobson at 410-786-7553. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: Reinstatement of a previously approved collection; Title of Information Collection: Social Security Office (SSO) Report of State Buy-in Problem; Use: Under Section 1843 of the Social Security Act, states may enter into an agreement with the Department of Health and Human Services to enroll eligible individuals in Medicare and pay their premiums. The purpose of the State Buy-in program is to assure that Medicaid is the payer of last resort by permitting a state to provide Medicare protection to certain groups of needy individuals, as part of the state's total assistance plan. State Buy-in also has the effect of transferring some medical costs for this population from the Medicaid program, which is partially state funded to the Medicare program, which is funded by the federal

government and individual premiums. Generally, the States Buy-in for individuals who meet the eligibility requirements for Medicare and are cash recipients or deemed cash recipients or categorically needy under Medicaid. In some cases, states may also include individuals who are not cash assistance recipients under the Medical Assistance Only group. The day-to-day operations of the State Buy-in program is accomplished through an automated data exchange process. The automated data exchange process is used to exchange Medicare and Buy-in entitlement information between the Social Security District Offices, Medicaid State Agencies and the Centers for Medicare & Medicaid Services. When problems arise however that cannot be resolved through the normal data exchange process, clerical actions are required. The CMS-1957, “SSO Report of State Buy-In Problem” is used to report Buy-in problems cases. The CMS-1957 is the only standardized form available for communications between the aforementioned agencies for the resolution of beneficiary complaints and inquiries regarding State Buy-in eligibility. Form Number: CMS-1957 (OCN: 0938-0035); Frequency: Reporting – Annually; Affected Public: Individuals and Households; Number of Respondents: 3,802; Total Annual Responses: 3,802; Total Annual Hours: 1,266. (For policy questions regarding this collection contact Lucia Diaz-Robinson at 410-247-6843. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: Revision of a currently approved collection. Title of Information Collection: Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) Competitive Bidding Program. Use: Since 1989, Medicare has been paying for durable medical equipment (DME) and supplies (other than customized items) using fee schedule amounts that are calculated for each item or category of DME

identified by a Healthcare Common Procedure Coding System code. Payments are based on the average supplier charges on Medicare claims from 1986 and 1987 and are updated annually on a factor legislated by Congress. For many years, the Government Accountability Office and the Office of Inspector General of the U.S. Department of Health and Human Services have reported that these fees are often highly inflated and that Medicare has paid higher than market rates for several different types of DME. Due to reports of Medicare overpayment of DME and supplies, Congress required that CMS conduct a competitive bidding demonstration project for these items. Accordingly, CMS implemented a demonstration project for this program from 1999-2002 which produced significant savings for beneficiaries and taxpayers without hindering access to DMEPOS and related services. Shortly after a successful demonstration of the competitive bidding program, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003 and mandated a phased-in approach to implement this program over the course of several years beginning in 2007 in 10 metropolitan statistical areas (MSAs). The statute specifically required the Secretary to establish and implement programs under which competitive bidding areas are established throughout the United States for contract award purposes for the furnishing of certain competitively priced items and services for which payment is made under Medicare Part B. This program is commonly known as the “Medicare DMEPOS Competitive Bidding Program.”

CMS conducted its first round of bidding for the Medicare DMEPOS Competitive Bidding Program in 2007 with the help of its contractor, the Competitive Bidding Implementation Contractor. CMS published a Request for Bids instructions and accompanying forms for suppliers to submit their bids to participate in the program. During this first round of

bidding, DMEPOS suppliers from across the U.S. submitted bids identifying the MSA(s) to service and the competitively bid item(s) they wished to furnish to Medicare beneficiaries. CMS evaluated these bids and contracted with those suppliers that met all program requirements. The first round of bidding was successfully implemented on July 1, 2008.

On July 15, 2008, however, Congress delayed this program in section 154 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA). MIPPA mandated certain changes to the competitive bidding program which included, but are not limited to: a delay of Rounds 1 (competition began in 2009) and 2 of the program (competition began in 2011 in 70 specific MSAs); the exclusion of Puerto Rico and negative pressure wound therapy from Round 1 and group 3 complex rehabilitative power wheelchairs from all rounds of competition; a process for providing feedback to suppliers regarding missing financial documentation; and a requirement for contract suppliers to disclose to CMS information regarding subcontracting relationships. Section 154 of the MIPPA specified that the competition for national mail order items and services may be phased in after 2010 and established a rule requiring that a bidder demonstrate that its bid covers 50 percent (or higher) of the types of diabetic testing strips, based on volume (the “50 percent rule”) for national mail order competitions. As required by MIPPA, CMS conducted the competition for the Round 1 Rebid in 2009. The Round 1 Rebid contracts and prices became effective on January 1, 2011.

The Affordable Care Act, enacted on March 23, 2010, expanded the Round 2 competition by adding an additional 21 MSAs, bringing the total MSAs for Round 2 to 91. The competition for Round 2 began in December 2011. CMS also began a competition for National Mail Order of Diabetic Testing Supplies at the same time as Round 2. The Round 2 and National Mail-

Order contracts and prices have a target implementation date of July 1, 2013.

The MMA requires the Secretary to re-compete contracts not less often than once every 3 years. Most Round 1 Rebid contracts will expire on December 31, 2013. (Round 1 Rebid contracts for mail-order diabetic testing supplies ended on December 31, 2012.) Consequently, we are currently in the process of re-competing the competitive bidding contracts in the Round 1 Rebid areas.

The most recent approval for this information collection request (ICR) was issued by OMB on October 10, 2012. Since then, CMS has decided to sequentially update the paperwork burden necessary to administer the program as it expands nationally and cycles through multiple rounds of competition. Specifically, we are now seeking to update our burden estimates for certain contract maintenance forms for Round 2 and the national mail-order competitions. These include Form C and the Contract Supplier's Disclosure of Subcontractors form. We are also requesting approval of two additional forms: the Change of Ownership (CHOW) Purchaser Form and the CHOW Contract Supplier Notification Form, which will be utilized in all rounds of competition. Finally, we are retaining without change Forms A, B, and D and their associated burden under this ICR. We note that the information collection for Forms A and B is already complete. We intend to continue use of the forms in future rounds of competition.

Form Number: CMS-10169 (OCN: 0938-1016). Frequency: Occasionally. Affected Public: Private Sector (business or other for-profits) and Individuals or households. Number of Respondents: 19,035. Total Annual Responses: 19,035. Total Annual Hours: 9,311. (For policy questions regarding this collection contact Michael Keane at 410-786-4495. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on **insert date 30 days after date of publication in the Federal Register.**

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-6974

E-mail: OIRA_submission@omb.eop.gov.

Dated: May 6, 2013

Martique Jones

Deputy Director, Regulations Development Group

Office of Strategic Operations and Regulatory Affairs

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